

No. 96-188



Supreme Court, U.S.

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**In the**  
**Supreme Court of the United States**

OCTOBER TERM, 1996

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GENERAL ELECTRIC COMPANY,  
WESTINGHOUSE ELECTRIC CORPORATION,  
AND MONSANTO COMPANY, *Petitioners,*

v.

ROBERT K. JOINER AND KAREN P. JOINER,  
*Respondents.*

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On Writ of Certiorari to the  
United States Court of Appeals  
for the Eleventh Circuit

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BRIEF OF THE DOW CHEMICAL  
COMPANY AS AMICUS CURIAE IN  
SUPPORT OF PETITIONERS

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26 pp

**QUESTION PRESENTED**

What is the standard of appellate review for trial court decisions excluding expert testimony under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993)?

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**INTEREST OF THE AMICUS CURIAE<sup>1</sup>**

Amicus The Dow Chemical Company ("Dow Chemical"), a Fortune 500 company, is a leading manufacturer of plastics, pesticides, herbicides, chlorinated materials, and consumer products, including ZIPLOC™, STYROFOAM™, and SARAN WRAP™. Over the past few decades, chemical manufacturers like Dow Chemical have experienced a

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<sup>1</sup> Pursuant to Rule 37.3 of the Rules of this Court, the parties have consented to the filing of this brief. The parties' letters of consent have been filed with the clerk of the Court.

marked increase in the volume of toxic tort litigation. And, alongside this explosion in tort litigation has arisen a substantial growth in the use of expert witnesses to propound theories that purport to demonstrate that a particular substance causes harm to those exposed to that substance. Because these experts are paid by the parties to present their theories to lay jurors, many courts have emphasized the need to be especially vigilant in considering the admissibility of their testimony. This Court's landmark opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), addressed this very issue and clarified the trial courts' role as a "gatekeeper," ensuring that the evidence submitted to the jury in a toxic tort case properly reflects valid scientific methodology and reasoning. Dow Chemical has a significant interest in the federal courts' continued adherence to their responsibilities as set forth in *Daubert*.

One prominent illustration of the need for careful screening of expert testimony in cases involving complex issues of science is the breast implant litigation. Thousands of lawsuits have been filed against Dow Chemical and its subsidiary, Dow Corning Corporation, alleging that breast implants manufactured by Dow Corning cause disease. Whether breast implants do, in fact, cause disease is a question that can be answered only by science. In resolving this question in the litigation context, *Daubert* established essential analytical tools that permit federal courts to ensure that theories of causation are genuine science, not illegitimate speculation. For example, late last year, after holding extensive *Daubert* hearings and taking testimony from neutral, court-appointed experts, a federal district judge in Oregon excluded all of plaintiffs' systemic disease causation experts in a recent breast implant case. *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996). Still, thousands of lawsuits remain pending against Dow Chemical. Should these lawsuits proceed to trial, it is vitally important to Dow Chemical that courts of appeals, in reviewing rulings

by trial courts on the admissibility of scientific evidence, are faithful to the fundamental principles established by this Court in *Daubert*.

## SUMMARY OF ARGUMENT

I. Although the clear majority of courts of appeals are in general agreement as to the standard of review of district court rulings on the admissibility of proposed expert scientific testimony, two circuits — the Eleventh in this case and the Third — have adopted a contrary position that requires a more stringent, "hard look" examination of district court decisions that *exclude* (but not those that admit) such testimony. While the Third Circuit invokes this standard only when the district court's evidentiary rulings directly result in judgment for the defendant, the Eleventh Circuit appears to apply heightened scrutiny to all decisions excluding expert scientific testimony.

The court of appeals' application of a bifurcated, result-oriented standard of review is contrary to this Court's recent holding that "the reviewing attitude that a court of appeals takes toward a district court decision should depend upon 'the respective institutional advantages of trial and appellate courts,' *not upon what standard of review will more likely produce a particular substantive result.*" *First Options v. Kaplan*, 115 S. Ct. 1920, 1926 (1995) (emphasis added) (citing *Salve Regina College v. Russell*, 499 U.S. 225, 231-233 (1991)). In the context of ruling on the admissibility of proposed expert scientific testimony, the relative "institutional advantages of trial and appellate courts" — and, hence, the applicable standard of review — do not depend in any way on the results of the trial court's analysis. The basic approach of the district judge applying this Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), is the same whether the court ultimately excludes or admits the testimony.



As it did in *Kaplan*, this Court should reject the court of appeals' attempt to adopt a "special" outcome-driven standard of review for a supposedly disfavored class of district court rulings that exclude expert testimony that fails to satisfy the reliability and relevance standards of the Federal Rules of Evidence.

II. The court of appeals' "hard look" review of district court decisions excluding expert scientific evidence reflects a fundamental misunderstanding of the Federal Rules of Evidence and this Court's opinion in *Daubert*. The "liberal thrust" of the Rules replaced many of the "rigid" aspects of prior evidence law with a new "flexib[ility]" (*Daubert*, 509 U.S. at 594), not a "let-it-all-in" philosophy. Under *Daubert*, the trial judge must exercise a gatekeeping function to "ensure that *any and all* scientific testimony or evidence admitted is not only relevant, but reliable." 509 U.S. at 589 (emphasis added). While it is easier under *Daubert* to present *legitimate* conflicting views to a jury because "general acceptance" no longer is an absolute prerequisite to admissibility, the proponent of the evidence must first establish the legitimacy of the proposed testimony by demonstrating that "the reasoning or methodology underlying the testimony is *scientifically valid*" and "properly can be *applied to the facts in issue*." *Id.* at 592 (emphasis added). In view of these formidable burdens imposed by the Federal Rules of Evidence, the court of appeals' assumption that it should be more skeptical of trial court rulings excluding scientific evidence than of rulings admitting such evidence must be rejected.

III. In undertaking its "hard look" review of the district court's decision to exclude respondents' expert testimony, the court of appeals endorsed an interpretation of *Daubert* and the Federal Rules of Evidence that is erroneous as a matter of law. The court of appeals suggests that this Court's statement that "[t]he focus \* \* \* must be solely on the principles and methodology, not on the conclusions that

they generate" (*Daubert*, 509 U.S. at 595) imposes a rigid compartmentalization according to which the district court must "view[] the bases of an expert's opinion as a whole" (Pet. App. at 13a) and may not examine "[w]hether the conclusions advanced from the stated premises in fact follow." *Id.* at 16a-17a (Birch, J., concurring). These restrictions undermine the rigorous empiricism which, as this Court has noted, "'distinguishes science from other fields of human inquiry'" (*Daubert*, 509 U.S. at 593) and prevent district judges from undertaking the critical inquiry into whether, as a matter of scientific method, the purported bases for an expert's opinion actually support that opinion.

In the absence of a rigorous examination of each step in an expert's analysis, courts and juries would have to rely on the word of hired experts that their opinions constituted "scientific knowledge" and "fit" an issue in the case. It simply is inconceivable that in distinguishing between "principles and methodology" on the one hand, and "conclusions" on the other, this Court abdicated to the expert himself the responsibility for ensuring compliance with the Federal Rules of Evidence. Rather, the district court, in the exercise of its gatekeeping duty, must make a preliminary determination that an expert's proposed opinion rests on "good grounds" all the way from hypothesis to ultimate conclusion about an issue in the case. This step establishes the trustworthiness of "any and all" opinions that are submitted to the jury. It then becomes the jury's role to choose which of the competing, scientifically-grounded conclusions is the correct one.

By applying a one-sided standard of appellate review that substantially favors admission over exclusion, the court of appeals has upset the "balance struck by the Rules of Evidence \* \* \* for the particularized resolution of legal disputes." *Daubert*, 509 U.S. at 597. This Court should restore *Daubert* to its proper role in keeping bad science out of the federal courts by (i) reiterating that the same standard

of review should apply regardless of the substantive outcome of the district court proceedings, and (ii) reversing the court of appeals' erroneous application of *Daubert* in this case.

### ARGUMENT

#### I. The Standard Of Review Of District Court Decisions On The Admissibility Of Expert Scientific Testimony Should Not Vary Depending On Whether The Testimony Was Admitted Or Excluded.

This Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993), clarified the trial court's "gatekeeping" duty to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." A question left open by the Court at that time, however, was the appropriate standard of appellate review of district court decisions under *Daubert*. See Margaret A. Berger, *Evidentiary Framework*, in Federal Judicial Center, *MANUAL ON SCIENTIFIC EVIDENCE* 53 (1994) ("Although *Daubert* rejects *Frye*, the opinion does not address the issue of the standard of review").

As Petitioners have noted, the clear majority of courts of appeals have accorded trial courts wide discretion in ruling on the admissibility of proposed expert scientific testimony, reviewing such decisions -- whether they result in exclusion or admission of the testimony -- under a "manifestly erroneous" or "abuse of discretion" standard. Pet. 6-10; Reply Br. 4. Only two circuits, the Eleventh and Third, have adopted a contrary position. See Pet. App. 1a-30a; *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717 (3d Cir. 1994). The standard followed in those two circuits is anomalous in two respects: (1) it entails a more stringent, "hard look" examination of the district court's rulings, and (2) it applies greater scrutiny only to rulings that *exclude* proposed expert scientific testimony.

As one federal judge wrote soon after the Third Circuit first adopted "hard look" review of district court decisions

excluding expert scientific testimony, this novel standard "appears to be without authority or precedent." Thomas A. Wiseman, Jr., *Judging the Expert*, 55 Ohio St. L.J. 1105, 1112 (1994). The Eleventh Circuit appears to have gone further even than the Third Circuit in extending the reach of this bifurcated, result-oriented standard of review. The Third Circuit invokes this heightened standard only when "the district court's exclusionary evidentiary rulings with respect to scientific opinion testimony will result in a summary or directed judgment." *Paoli R.R. Yard*, 35 F.3d at 750. The Eleventh Circuit, on the other hand, appears to apply "hard look" review to all decisions excluding expert testimony, regardless of whether summary or directed judgment follows directly from the trial court's evidentiary rulings. See Pet. App. 4a-5a.

Perhaps the most compelling reason that the other courts of appeals have declined to follow the lead of the Third and Eleventh Circuits is this Court's admonition that standards of appellate review should *not* be governed by the result of the proceedings in the district court. As the Court observed in *Salve Regina College v. Russell*, 499 U.S. 225, 233 (1991), the appellate standard of review is a neutral device designed to reflect "the respective institutional advantages of trial and appellate courts," not an outcome-driven means of promoting substantive policies. In the context of rulings on the admissibility of scientific evidence, the questions that arise in the district court involve both law and fact, and the "institutional advantages" implicated depend to a large degree upon the circumstances. For present purposes, however, the more salient point is that the basic inquiries undertaken by the district court in faithfully applying *Daubert* (and its progeny) to the specific, fact-laden testimony offered in a given case are identical whether the court ultimately excludes or admits the testimony. Thus, the relative "institutional advantages of trial and appellate courts" in addressing the evidentiary questions posed by *Daubert*, and therefore the standard of



review required, do not depend in any way upon the results of the trial court's *Daubert* analysis.

Moreover, even if the Eleventh Circuit were correct in assuming that there is a policy "preference for admissibility" (Pet. App. 4a) of scientific testimony (which, as we show below, is not the case), there is no legitimate ground for changing the appellate standard of review to advance that policy preference. Indeed, in a recent case, *First Options, Inc. v. Kaplan*, 115 S. Ct. 1920, 1926 (1995), this Court expressly disapproved a similar effort by the Eleventh Circuit to adopt a bifurcated standard of review that reflected the court of appeals' substantive policy views. In *Robbins v. Day*, 954 F.2d 679, 682 (11th Cir. 1992), the court held that the "national policy favoring arbitration" "presumes that reviewing courts will confirm arbitration awards" and justifies an especially lenient "abuse of discretion" standard when reviewing district court decisions that confirm arbitration awards. Decisions that set aside such awards, however, "go[] against the presumption" and therefore must be "review[ed] de novo to protect the integrity of the arbitration process." *Ibid.*

As this Court noted in *Kaplan*, no other court of appeals had adopted the Eleventh Circuit's novel approach. 115 S. Ct. at 1926. This Court, too, declined to import substantive policy concerns into the standard of review, holding instead that "the majority of Circuits is right in saying that courts of appeals should apply ordinary, not special, standards when reviewing district court decisions upholding arbitration awards." *Id.* As the Court explained,

"For one thing, it is undesirable to make the law more complicated by proliferating review standards without good reasons. More importantly, the reviewing attitude that a court of appeals takes toward a district court decision should depend upon 'the respective institutional advantages of trial and appel-

late courts,' not upon what standard of review will more likely produce a particular substantive result."

*Ibid.* (emphasis added) (citing *Salve Regina College*, 499 U.S. at 231-233). The Court further noted that despite the deference owed to agency interpretations under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984), "no one, to our knowledge, has suggested that this policy of giving leeway to agencies means that a court of appeals should give extra leeway to a district court decision that upholds an agency." *Kaplan*, 115 S. Ct. at 1926.

In *Kaplan*, this Court unmistakably "put to rest any notion that the standard of review turns upon whether the district court vacated or confirmed the award. In light of *Kaplan*, it is clear that the same standard of appellate review applies regardless of whether the district court confirms or sets aside the arbitration award." *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Jaros*, 70 F.3d 418, 420 (6th Cir. 1995). As it did in *Kaplan*, this Court should set aside an attempt by the Eleventh Circuit to adopt a "special" standard of review for a purportedly disfavored class of district court rulings — namely, those that exclude expert testimony that fails to satisfy the reliability and relevance standards of the Federal Rules of Evidence.

## II. The One-Sided Standard Of Review Adopted By The Eleventh Circuit Has No Support In The Federal Rules Of Evidence And Is Contrary To This Court's Teachings In *Daubert*.

Even absent this Court's guidance in *Kaplan*, there would be no justification for upholding a bifurcated, result-oriented standard of review of trial court rulings on the admissibility of scientific evidence. In applying a heightened level of scrutiny to the exclusionary rulings of district courts, the Third and Eleventh Circuits have erroneously concluded that the Federal Rules of Evidence and this Court's opinion

in *Daubert* mandate a global relaxation and liberalization of the admissibility requirements for expert scientific evidence — a mandate which requires appellate courts to be especially wary when trial courts conclude that proposed testimony does not satisfy *Daubert*'s requirements of relevance and reliability. As explained below, this approach to the admissibility of scientific evidence mistakenly equates the so-called "liberal" approach of the Federal Rules with a "let-it-all-in" philosophy that cannot be reconciled with this Court's interpretation of the Rules in *Daubert*.

To be sure, *Daubert* did "loosen the strictures of *Frye* and make it easier to present *legitimate* conflicting views of experts for the jury's consideration." Pet. App. 7a (emphasis added). Thus, consistent with its prior observation that the Federal Rules encompass a "general approach of relaxing the traditional barriers to 'opinion' testimony" (*Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 169 (1988)), this Court held that the effect of the "liberal thrust" of the Federal Rules was to replace the "rigid 'general acceptance' requirement" of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), with a more "flexible" approach governed by the numerous specific Rules that relate to the admissibility of expert scientific testimony. *Daubert*, 509 U.S. at 594. But the Court's discussion of the rigorous standards for reliability and relevance imposed by several interrelated Rules of Evidence (*id.* at 595) belies the Eleventh Circuit's conclusion that *Daubert* somehow established a "lower threshold" for expert scientific opinions. Pet. App. 8a. As Chief Judge Posner of the Seventh Circuit has written, one part of the *Daubert* opinion held that "the opinion evidence of reputable scientists is admissible in evidence in a federal trial even if the particular methods they used in arriving at their opinion are not yet accepted as canonical in their branch of the scientific community." *Braun v. Lorillard, Inc.*, 84 F.3d 230, 234 (7th Cir. 1996). But, Judge Posner continued, "that is only part of the holding of *Daubert*. The other part

is that the district court is responsible for making sure that when scientists testify in court they adhere to the same standards of intellectual rigor that are demanded in their professional work." *Ibid.*; see also National Academy of Sciences, SCIENCE AND CREATIONISM: A VIEW FROM THE NATIONAL ACADEMY OF SCIENCES 8 (1984) ("Rigor in the testing of hypotheses is the heart of science").

Thus, while the Federal Rules of Evidence relaxed certain outdated limitations on the admissibility of evidence — for example, displacing *Frye*'s rigid requirement that novel scientific evidence gain "general acceptance" in the relevant field as an "absolute prerequisite to admissibility" — they also imposed a gatekeeping responsibility on the district judge, who "must ensure that *any and all* scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 588, 589 (emphasis added). In particular, Rule 104 specifically provides that the district court shall determine "[p]reliminary questions concerning \* \* \* the admissibility of evidence." Rule 702, in turn, establishes the twin prongs of reliability and relevance identified and explained in *Daubert*. And the other rules identified by this Court as bearing on the scientific evidence inquiry — Rules 403, 703, and 706 — also highlight the enhanced preliminary role of the district court under the Federal Rules of Evidence. Applying these Rules as an integrated whole, the district judge must undertake "a preliminary assessment of whether the reasoning or methodology underlying the testimony is *scientifically valid* and of whether that reasoning or methodology properly can be *applied to the facts in issue*." *Daubert*, 509 U.S. at 592-593 (emphasis added).

With these principles in mind, the Eleventh Circuit's notion that the changes brought about by the Federal Rules (as construed by this Court in *Daubert*) mandate a more skeptical review of trial court rulings excluding scientific evidence than of rulings admitting such evidence must be



rejected. While it is true that *Daubert* makes it easier to present legitimate conflicting views of experts for the jury's consideration because "general acceptance" no longer is a prerequisite to admissibility, *Daubert* also establishes a rigorous threshold inquiry into whether the proffered testimony is, in fact, legitimate. Indeed, if there is one lesson that the federal courts have learned from *Daubert*, it is that they must demand rigor from the scientists who propose to testify in their courtrooms. See, e.g., *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 198 (5th Cir. 1996) (observing that the goal of *Daubert* "has been to bring more rigorous scientific study into the expression of legal opinions offered in court by scientific and medical professionals"); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1315 (9th Cir. 1995) ("Federal judges ruling on the admissibility of expert scientific testimony face a far more complex and daunting task in a post-*Daubert* world than before"); *Wilson v. City of Chicago*, 6 F.3d 1233, 1238-1239 (7th Cir. 1993) (*Daubert* "shifted to the trial judge the responsibility for keeping 'junk science' out of the courtroom"); *In re Joint E. & S. Dists. Asbestos Litig.*, 151 F.R.D. 540, 545 (E. & S.D.N.Y. 1993) (noting that *Daubert* has "broadened and sharpened the trial judge's gatekeeper role to determine whether an expert's testimony both rests on a reliable foundation and is relevant to the task at hand"); see also American College of Trial Lawyers, *Standards and Procedures for Determining the Admissibility of Expert Evidence After Daubert*, 157 F.R.D. 571, 571 (1994) ("*Daubert* clearly requires trial judges to subject expert evidence to more penetrating pretrial scrutiny"); David E. Bernstein, *The Admissibility of Scientific Evidence After Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 15 Cardozo L. Rev. 2139, 2139 (1994) ("most federal courts are interpreting *Daubert* as

giving them wide authority to restrict the scope of admissible scientific evidence in toxic tort litigation").<sup>2</sup>

In sum, far from creating a "lower threshold" for science experts, as the court of appeals erroneously assumed, *Daubert* imposes formidable burdens on experts to demonstrate the reliability and relevance of their theories to the satisfaction of the district court.

### III. In Undertaking Its "Hard Look" Review Of The District Court's Decision To Exclude Respondents' Expert Testimony, The Court Of Appeals Improperly Truncated The District Court's Duty Under *Daubert* To Ensure The Reliability And Relevance Of Proffered Expert Scientific Testimony.

In the exercise of its "hard look" review of the district court's exclusion of the respondents' causation experts, the court of appeals in this case reexamined the proffered opinions and the bases cited for them, and concluded that the district court had improperly assessed the admissibility of the testimony. In so doing, the court of appeals endorsed an interpretation of *Daubert* and the Federal Rules of Evidence that is erroneous as a matter of law. The court's flawed application of this Court's teachings results in a watered down application of the district court's gatekeeping responsibilities that severely undercuts the objective of the limitations on the use of expert testimony in the Federal Rules — to "ensur[e] that an expert's testimony both rests on a reliable

<sup>2</sup> The trial court's gatekeeping function is even more critical where, as here, the litigation involves an alleged toxic tort. As Judge Weinstein has observed, "[t]he uncertainty of the evidence" in toxic tort cases, "dependent as it is upon speculative scientific hypotheses and epidemiological studies, creates a special need for robust screening of experts." *In re Agent Orange Prods. Liab. Litig.*, 611 F. Supp. 1223, 1260 (E.D.N.Y. 1985), *aff'd*, 818 F.2d 187 (2d Cir. 1987).

foundation and is relevant to the task at hand." *Daubert*, 509 U.S. at 597. It is imperative that this Court not place its imprimatur on the decision or reasoning of the court of appeals below.

At the heart of the dispute between the district court and the court of appeals in this case is the meaning of this Court's statement that "[t]he focus \* \* \* must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. Both the majority and concurring opinions in the court of appeals suggest a rigid compartmentalization of the trial court's review of the proposed expert's "methodology" and his "conclusions." Thus, according to the majority, in conducting its inquiry, the district court must "view[] the bases of an expert's opinion as a whole" (Pet. App. 13a), instead of reviewing "individual studies" or "pieces of evidence." *Id.* at 11a-12a. Or, as Judge Birch observed, determining "[w]hether the conclusions advanced from the stated premises in fact follow" is not part of the district court's gatekeeping role. *Id.* at 16a-17a.

In imposing a rigid distinction between "principles and methodology" on the one hand, and "conclusions" on the other, and on that basis directing district courts to look only to the "bases of an expert's opinion as a whole" (Pet. App. 12a-13a), the court of appeals misapprehended both the nature of science and the rigor with which federal courts must ascertain the "good grounds" for an expert's opinion. Science, as this Court recognized in *Daubert*, "is not an encyclopedic body of knowledge about the universe." 509 U.S. at 590 (quoting Brief for American Association for the Advancement of Science et al. as Amicus Curiae at 7-8). Nor is it simply raw data or bare conclusions. Rather, science "represents a process for proposing and refining theoretical explanations about the world that are subject to further testing and refinement." *Ibid.* (emphasis in original). As scientists work to prove (or disprove) various theories, they

build on their own and each others' work in progressing, often one step at a time, from hypothesis to conclusion. While "arguably, there are no certainties in science" (*ibid.*), the rigorous empiricism of the scientific method "is what distinguishes science from other fields of human inquiry." *Id.* at 593.

Unfortunately, the Eleventh Circuit approach undermines this empiricism by preventing trial judges from undertaking a critical inquiry that goes to the essence of what *Daubert* is all about — namely, whether, as a matter of scientific method, the purported bases for an expert's opinion actually support that opinion. By forcing the district court to clump together all of an expert's data (and other bases for his opinion), the court of appeals frustrates any inquiry into whether the expert actually has connected that data to his ultimate conclusions. Indeed, in view of Judge Smith's unassailable observation that "[a] single expert may offer several opinions to reach his ultimate conclusion" (Pet. App. 17a (Smith, J., dissenting)), one wonders precisely how the court of appeals envisions district courts going about the often messy business of "separat[ing] the wheat from the chaff" (*id.* at 22a) while treating the bases of that expert's testimony as an amalgamated whole.

As several courts of appeals have recognized, *Daubert* requires gatekeepers to ascertain that jurors are exposed only to real science, not merely the unsupported conclusions of well-credentialed scientists, when they resolve difficult issues of causation. See, e.g., *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir. 1996) (Posner, C.J.) ("an expert who supplies nothing but a bottom line supplies nothing of value to the judicial process"); *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) (Kozinski, J.) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough."). Close scrutiny of not only the data or underlying bases of expert



scientific opinions, but also the reasoning that connects the data to an issue in the case, prevents clever experts-for-hire from tainting the jury with ultimate conclusions that do not follow from the purported bases for those conclusions. As one respected observer noted,

"Too often, experts provide only disjointed data wrapped in jargon with no underlying theory or explanation. After listing the facts and studies on which they rely, they simply conclude that according to their medical judgment such an array of information points to causation. \* \* \* Such gobbledygook is not useful or valid science at any level of certainty, and should be excluded as inadmissible."

Bert Black, *The Supreme Court's View of Science: Has Daubert Exorcised the Certainty Demon?*, 15 Cardozo L. Rev. 2129, 2132-2133 (1994) (emphasis in original).

Thus, it is not surprising that most courts applying *Daubert* have agreed that the distinction between methodology and conclusions upon which the Eleventh Circuit relied so heavily "has only limited practical import" (*Paoli R.R. Yard*, 35 F.3d at 746), and does not inhibit the district court's duty to sift through the stated bases for an expert's conclusion to confirm that his reasoning is sound (i.e., that it is "scientific knowledge" and that it "fits" the case). See, e.g., *Raynor v. Merrell Pharmaceuticals, Inc.*, 104 F.3d 1371, 1374-1375 (D.C. Cir. 1997) (noting that the line between methodology and conclusions "is not all that clear, as propositions may be formulated as conclusions or methodologies with comparatively minor linguistic adjustment"). In the instant case, for example, one of the pivotal questions can be framed as whether it is methodologically sound to draw an inference that PCBs cause small cell lung cancer in humans from (1) testimony based on erroneous assumptions as to exposure and (2) animal studies in the absence of any reliable scientific basis for extrapolating

conclusions based on those studies to humans. Pet. App. 52a-62a.

In assessing whether the expert's conclusions actually follow from the bases upon which the expert purported to rely, it is important to first recognize that the process of generating valid conclusions that form the basis for admissible testimony of a scientific expert frequently involves multiple, reasoned extrapolations from studies or data. See Bernstein, *supra*, 15 Cardozo L. Rev. at 2165-2166. Faithfulness to *Daubert*'s "reliability" prong requires courts to rigorously examine each link in the chain of reasoning or methodology underlying the expert's proposed testimony. As the Third Circuit has explained,

"*Daubert*'s requirement that the expert testify to scientific knowledge — conclusions supported by good grounds for each step in the analysis — means that any step that renders the analysis unreliable under the *Daubert* factors renders the expert's testimony inadmissible. This is true whether the step completely changes a reliable methodology or merely misapplies that methodology."

*Paoli R.R. Yard*, 35 F.3d at 745 (emphasis in original); see also *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, 309-310 (5th Cir. 1989) ("Confronted \* \* \* with difficult medical questions, courts must critically evaluate the reasoning process by which the experts connect data to their conclusions in order for courts to consistently and rationally resolve the disputes before them"). Indeed, the failure to examine the expert's connective reasoning reduces the court (and the jury) to "accept[ing] blindly the expert's word to fill the analytical gap between proffered 'scientific knowledge' and the expert's conclusions." Pet. App. 18a (Smith, J., dissenting).

Rule 702's "helpfulness" or "fit" standard also "requires a valid scientific connection to the pertinent inquiry as a

precondition to admissibility." *Daubert*, 509 U.S. at 591-592; see also *Paoli R.R. Yard*, 35 F.3d at 743 (observing that under "fit" analysis, the "expert's proposed testimony" must be "scientific knowledge for purposes of the case" at bar). In some cases, including this one, an expert may rely on science that is reliable as far as it goes, but nevertheless ought to be excluded on "fit" grounds because "the analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue \* \* \* is too wide." *Conde v. Velsicol Chem. Corp.*, 24 F.3d 809, 814 (6th Cir. 1994). As the Third Circuit explained in discussing perhaps the most common "fit" problem:

"[I]n order for animal studies to be admissible to prove causation in humans, there must be good grounds to extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about the animals themselves. Thus, the requirement of reliability, or 'good grounds,' extends to each step in an expert's analysis all the way through the step that connects the work of the expert to the particular case."

*Paoli R.R. Yard*, 35 F.3d at 743; see also *Barrett v. Atlantic Richfield Co.*, 95 F.3d 375, 382 (5th Cir. 1996) ("it is clear that [plaintiff's expert's] testimony could not establish with any scientific reliability whether there was an exposure parallel between the cotton rats and human beings, and we therefore affirm the district court's decision not to admit the testimony"). Thus, for example, even if the use of animal studies in a particular case might be appropriate under Rule 703, the conclusions drawn from specific animal studies about human causation may be unreliable and/or irrelevant under Rule 702 in the absence of valid connective reasoning.

It is true that "a challenge to 'fit' is very close to a challenge to the expert's ultimate conclusion about the particular case." *Paoli R.R. Yard*, 35 F.3d at 746. But the basis for exclusion on "fit" grounds is not the anomalous

nature of the conclusion itself, but rather an error or omission in the expert's connective reasoning that undermines the legitimacy (i.e., the relevance and/or reliability) of the proposed testimony. In many cases, two or more competing opinions will be deemed "scientific," and the court may not invade the province of the jury to decide which conclusion is the correct one. Here, contrary to the court of appeals' view, the district court did not draw any *scientific* conclusions at all, nor did it exclude any of the proffered testimony on the type of "general acceptance" grounds that were relaxed in *Daubert*. Rather, the district court simply examined the foundations for the experts' opinions, the methodologies they followed, and the connective reasoning linking their underlying premises to their ultimate conclusions, and reached the *legal* conclusion that the purportedly "scientific" conclusions propounded by the plaintiffs' experts either were not founded on reliable methodology or were not relevant to issues in the case. This is precisely the type of inquiry envisioned in this Court's opinion in *Daubert*.

\* \* \* \* \*

As this Court recognized, faithful adherence to the teachings of *Daubert* "inevitably on occasion will prevent the jury from learning of authentic insights and innovations," but nevertheless represents "the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes." *Daubert*, 509 U.S. at 597. In this case, the court of appeals has upset this balance through the operation of a one-sided standard of appellate review that substantively favors admission over exclusion. Furthermore, in applying its "hard look" review, the court undertook no more than a halfhearted examination of an expert's methodology and connective reasoning. This dilution of *Daubert*, if upheld by this Court, raises the specter of self-proclaimed experts evading *Daubert*'s gatekeeping hurdle so long as they are, at some level, performing a scientific endeavor, however



distantly related to any genuine issue in the case. This Court should restore *Daubert* to its proper role in keeping bad science out of the federal courts by (i) reiterating that the same standard of review should apply regardless of the substantive outcome of the district court proceedings, and (ii) reversing the court of appeals' erroneous application of *Daubert* in this case.

### CONCLUSION

The judgment of the United States Court of Appeals for the Eleventh Circuit should be reversed.

Respectfully submitted.

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